

432-1463

12/23/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

December 23, 2013

Dr. Norma C. Pangilinan
Bayer Environmental Science
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: Label notification to add restrictions for the state of Oregon, per PRN 98-10

Dear Dr. Pangilinan:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10, dated December 10, 2013 for "Merit Injectable Capsules" EPA Registration No. 432-1463.

The Registration Division (RD) has conducted a review of the request for applicability under PRN 98-10 and finds that the changes requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please contact me directly at 703-308-8735 or email me at chao.julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie A. Chao".

Julie A. Chao
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

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Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 432-1463	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Merit Injectable Capsules	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) Bayer Environmental Science 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION DEC 23 2013
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

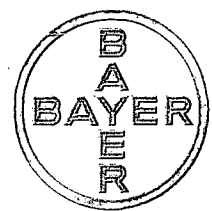
To revise label to add the pollinator protection statement restricting use on linden trees that is being required by the Oregon Department of Agriculture

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
If "Yes" Unit Packaging wgt. 3 mL and 6 mL		No. per container 25, 50, 100	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name NORMA C. PANGILINAN	Title Manager, Registrations	Telephone No. (Include Area Code) 919-549-2428
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) CC CC
2. Signature 	3. Title Manager, Registrations	
4. Typed Name Norma C. Pangilinan, Ph.D.	5. Date December 10, 2013	



Bayer CropScience

Document Processing Desk (NOTIF)
EPA - Office of Pesticide Programs (7504P)
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202

Attn: Venus Eagle,
Product Manager Team 1
Registration Division, Insecticide-Rodenticide

NOTIFICATION

DEC 23 2013

Subject: Label Notification with Oregon Dept of Agriculture Requirement
- Merit Injectable Capsules (EPA Reg. No. 432-1463)

December 10, 2013

Dear Ms. Eagle

Bayer CropScience
P. O. Box 12014
2 TW Alexander Drive
Research Triangle Park
NC 27709
Tel: 919 549-2000

The enclosed Notification is being submitted to add the pollinator protection statement restricting use on linden trees that is being required by the Oregon Department of Agriculture.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

The following documents are enclosed in support of this application:

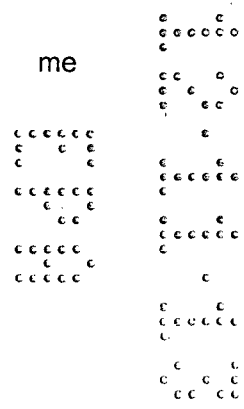
1. Completed EPA Form 8570-1
2. ~~Two~~ copies of the revised product label plus one highlighted copy tracking revision to label.

Please do not hesitate to call (919-549-2428) or e-mail me (norma.pangilinan@bayer.com), if you have any questions.

Sincerely,

BAYER ENVIRONMENTAL SCIENCE
A DIVISION OF BAYER CROPSCIENCE

NORMA C. PANGILINAN, Ph.D,
Registrations Manager





Bayer Environmental Science

Merit[®] Injectable Capsules

For injection into trees in nurseries, greenhouses, and interior and exterior plantscapes, and in private, municipal, state, and national forested areas.

ACTIVE INGREDIENT:

*Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine..... 17.1%

OTHER INGREDIENTS:..... 82.9%

100.0%

EPA Reg. No. 432-1463

EPA Est. No.432-TX-1

STOP - Read the label before use.

Keep out of reach of children.

CAUTION

FIRST AID	
If on skin or clothing:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
In case of emergency call toll free the Bayer Environmental Science Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note To Physician: No specific antidote is available. Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wear long-sleeved shirt and long pants, socks, shoes, chemical-resistant gloves, and protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Personal Protective Equipment (PPE):

Applicators and Other Handlers who handle this product must wear:

- Long-sleeved shirt and long pants
- Chemical resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber or natural rubber
- Shoes plus socks

Follow manufacturer's instructions for cleaning/ maintaining personal protective equipment, PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

NOTIFICATION

DEC 23 2013

User Safety Recommendations

User should:

- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.
- Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-334-7577 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

This product is highly toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

This product is highly toxic to bees exposed to direct treatment or residues on blooming trees and shrubs.

Do not formulate this product into other end-use products.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area. Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage. If container is leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed for pesticides below. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer Environmental Science Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer Environmental Science Emergency Response Telephone No. is 1-800-334-7577 or contact Chemtrec at 800-424-9300.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: No refillable container. Do not reuse or refill this container. Do not empty microinjection units. Place used microinjection units in the heavy-duty plastic bag which accompanies each carton of injector units. The bag must be properly sealed, placed into the original shipping carton, and returned freight prepaid for disposal to: Tree Tech Microinjection Systems, 950 SE 215th Ave, Morriston, FL 32668.

APPLICATION TO TREES

Merit Injectable Capsules can be used to control a variety of insect pests of ornamental or forest trees. Pests controlled include aphids, whiteflies, soft scales, adelgids, leafhoppers, lace bugs, mealybugs, psyllids, leaf-feeding beetles, sawflies, borers, and leafmining flies, beetles, and wasps. Merit Injectable Capsules also can be used for suppression of thrips and armored scales. Merit Injectable Capsules can be used as directed on ornamental trees in residential areas, business and office complexes, shopping complexes, multi-family residential complexes, golf courses, airports, cemeteries, parks, playgrounds, and athletic fields. Merit Injectable Capsules also can be used in commercial forestry production, nurseries, greenhouses, and in state, federal, county and local recreational forests.

The active ingredient in Merit Injectable Capsules has sufficient residual activity so that applications can be made preceding the attack of the trees by target pests. Merit Injectable Capsules also controls existing infestations of most labeled pests; control of existing infestations of borers and other difficult-to-control pests can be achieved if the level of infestation is not excessively severe at the time of application. If the level of infestation is severe, the high label rate for the targeted pest is recommended.

Systemic activity occurs only after the active ingredient is translocated upwards in the tree. In some cases, translocation can take 10 days or longer, depending on the transpiration rate of the treated plant.

The need for an application can be based on historical monitoring of the site, previous records or experiences, current season adult trapping or other methods. For best results (i.e., to ensure uptake), application should be made when the trees are actively transpiring.

NOTE: Not for use on trees where the fruits and/or nuts are consumed. Do not apply more than once per year per tree.

GENERAL DIRECTIONS

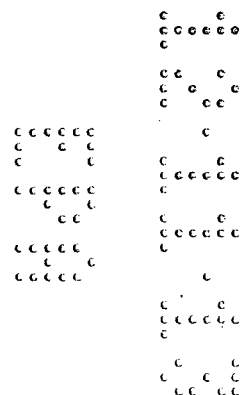
Applying Merit Injectable Capsules using the Tree Tech microinjection system:

Installing Microinjection Units

1. Determine the number of microinjection units to be installed based upon 1) the target insect pest(s), and 2) the registered dosage rate as administered by proper spacing of microinjection units around the stem circumference. Unless otherwise noted, microinjection units should be installed in the stem and root flares every 6 inches around the trunk near the ground line, i.e., 6.0-to-8.0 inches (15-to-20 cm) from the soil surface.
2. Using a portable electric drill (600-800 rpm capacity is preferred) with a sharp, clean 11/64-in. (0.4-cm) bit, the installer should drill a hole at the correct stem circumference spacing to a depth of 1/4-to-1/2 in. (0.60-to-1.3 cm) into the wood (xylem) under the bark. A slight downwardly angle is recommended for more complete drainage of the microinjection unit.
3. After reaching the proper depth range, the drill bit should be withdrawn carefully to avoid dislodging bark fragments around the exterior opening of the hole. The rear barrel portion of the microinjection unit should be compressed partially (about 1/2 in. or 1/3 cm.) The microinjection unit should be inserted into the hole and the rear barrel portion compressed further without engaging the locking mechanism and barrel segments. Placing the plastic installation cap over the rear barrel end, strike the cap with a plastic hammer to seat the microinjection unit firmly in the hole. If the microinjection unit is not properly positioned in the hole, strike the cap again until correctly seated. By striking the microinjection unit, the back end of the feeder tip is forced back into the funnel-shaped section dislodging a septum that allows the Merit Injectable Capsules solution to flow from the microinjection unit into the tree.
4. When the microinjection unit is positioned correctly in the tree and the internal septum is dislodged to permit the flow of Merit Injectable Capsules, remove the cap and, if necessary, push the rear barrel portion of the unit further downwardly until it is flush with the edge of the Locking mechanism. This engages the locking mechanism that pressurizes the microinjection unit and assists in the evacuation of Merit Injectable Capsules from the microinjection unit and movement into the vascular system of the tree.
5. Each hole should be drilled and a microinjection unit installed without delay. After the unit is properly seated, it should be activated. This sequence minimizes the flow of tree sap or resin into the hole prior to uptake of Merit Injectable Capsules.

When properly installed, the microinjection unit generates internal pressure resulting in the flow of Merit Injectable Capsules through the dispenser tube. The microinjection unit must never be activated unless installed correctly and securely in the tree to be treated.

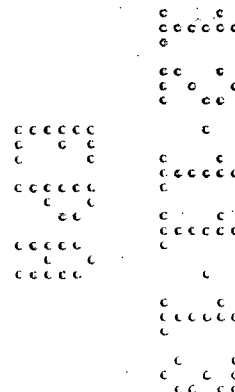
Occasionally microinjection units containing Merit Injectable Capsules may require up to several hours or more to empty depending on the health of the treated tree and local weather conditions. Never assume that microinjection units have depressurized completely because they appear nearly empty or empty. The individual should then cover the microinjection unit with one hand near the point of insertion into the stem while grasping the barrel end of the microinjection unit with the other hand. The injector should be turned slightly as it is slowly withdrawn from the tree. Careful removal of microinjection units should prevent accidental spillage of Merit Injectable Capsules and subsequent exposure to the installer.



[Alternate Text for the 3mL Capsule]

RECOMMENDED APPLICATIONS	
Trees and shrubs (greater than 2" diameter or 6.25 inches circumference, at chest height) For bee-pollinated dicotyledenous trees, applications should be made post-bloom. Restriction: Do not apply this product, by any application method, to linden, basswood, or other Tilia species.	
Pest	Dosage
Adelgids Aphids Japanese beetles adults Lacebugs Leaf-feeding beetles (including elm and viburnum leaf beetles) Leafhoppers Leafminers Mealybugs Psyllids Soft scales Thrips (suppression) Whiteflies	One Merit Injectable capsule per 2-4 inches of cumulative trunk diameter (6.25-12.5 inches of circumference) at chest height (54" from ground). Space injection holes equidistantly around the circumference of the tree.
Armored scales (suppression) Roundheaded borers (incl. Eucalyptus longhorned borer) Flatheaded borers (including bronze birch borer, alder borer, Pine tip moth larvae Royal palm bug Sawfly larvae	One Merit Injectable capsule per 2 inches of cumulative trunk diameter (6.25 inches of circumference) at chest height (54" from ground). Space injection holes equidistantly around the circumference of the tree.

For trees greater than 12" diameter (37.5 inches circumference), or if trees are already infested, the highest label rate specified for control of targeted pests is recommended (i.e., one capsule for every 2 inches of trunk diameter, or 6.25 inches of trunk circumference). For trees larger than 24" diameter (75 inches circumference), always use the 2-inch diameter spacing (6.25 inches circumference) for the targeted pest.



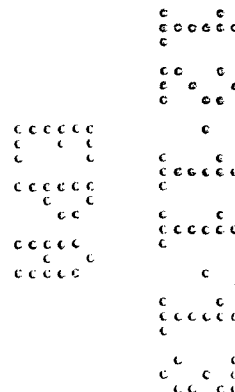
[Alternate Text for the 6mL Capsule]

RECOMMENDED APPLICATIONS	
Trees and shrubs (greater than 2" diameter or 6.25 inches circumference, at chest height) For bee-pollinated dicotyledenous trees, applications should be made post-bloom. Restriction: Do not apply this product, by any application method, to linden, basswood, or other Tilia species.	
Pest	Dosage
Adelgids Aphids Japanese beetles adults Lacebugs Leaf beetles (including elm and viburnum leaf beetles) Leafhoppers (including glassy-winged sharpshooter) Leafmining flies and wasps Mealybugs Psyllids Soft scales Whiteflies	One Merit Injectable capsule per 2-4 inches of cumulative trunk diameter (6.25-12.5 inches of circumference) at chest height (54" from ground). Space injection holes equidistantly around the circumference of the tree.
Armored scales (suppression) Roundheaded borers (incl. Eucalyptus longhorned borer) Flatheaded borers (including bronze birch borer, alder borer, and emerald ash borer) Leafmining beetles Pine tip moth larvae Royal palm bug Sawfly larvae Thrips (suppression)	One Merit Injectable capsule per 2-4 inches of cumulative trunk diameter (6.25-12.5 inches of circumference) at chest height (54" from ground). Space injection holes equidistantly around the circumference of the tree. For trees greater than 24" diameter, or if trees are already heavily infested, the highest label rate specified for control of targeted pests is recommended (i.e., one capsule for every 2 inches of trunk diameter, [6.25 inches of trunk circumference]).

RESTRICTIONS

Do not use on fruit or nut trees intended for food uses.

Restriction: Do not apply this product, by any application method, to linden, basswood, or other Tilia species.



IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of liability before using this product.

If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following conditions, disclaimer of warranties and limitations of liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, because of manner of use and other factors beyond Bayer CropScience LP's control it is impossible for Bayer CropScience LP to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. Bayer CropScience LP disclaims any liability whatsoever for special, incidental or consequential damages, resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS: 600 mL (6 mL x 100 capsules/box) or 20.29 fl. oz.

300 mL (6 mL x 50 capsules/box) or (3 mL x 100 capsules/box)] or 10.15 fl. oz

150 mL (6 mL x 25 capsules/box) or (3 mL x 50 capsules/box) or 5.07 fl. oz

PRODUCED FOR



Bayer Environmental Science

A Division of Bayer CropScience LP
2 T. W. Alexander Drive
Research Triangle Park, NC 27709

Merit Injectable Capsules (Pending) 12-05-2013

